JOB DESCRIPTION & PERSON SPECIFICATION

Job title: Clinical Trial Manager

GOSH profile

Great Ormond Street Hospital for Children NHS Foundation Trust (GOSH) is an international centre of excellence in child healthcare. GOSH is an acute specialist paediatric hospital with a mission to provide world-class care to children and young people with rare, complex and difficult-to-treat conditions.

Together with our research partner, the UCL Great Ormond Street Institute of Child Health, we form the UK's only academic Biomedical Research Centre specialising in paediatrics. Since its formation in 1852, the hospital has been dedicated to children's healthcare and to finding new and better ways to treat childhood illnesses.

Great Ormond Street Hospital receives nearly 300,000 patient visits (inpatient admissions or outpatient appointments) every year (figures from 2018/19). Most of the children we care for are referred from other hospitals throughout the UK and overseas. There are 60 nationally recognised clinical specialities at GOSH; the UK's widest range of specialist health services for children on one site. More than half of our patients come from outside London and GOSH is the largest paediatric centre in the UK for services including paediatric intensive care and cardiac surgery.

Through carrying out research with the UCL Great Ormond Street Institute of Child Health, University of London and international partners, GOSH has developed a number of new clinical treatments and techniques that are used around the world.

The UK's only academic Biomedical Research Centre (BRC) specialising in paediatrics is a collaboration between GOSH and UCL Great Ormond Street Institute of Child Health. We are a member of University College London (UCL) Partners, joining UCL with a number of other hospitals – an alliance for world-class research benefitting patients.

In partnership with six other NHS trusts, we are the lead provider for North Thames Genomics Medicine Centre, part of the national 100,000 Genomes Project.

Great Ormond Street Hospital at a glance

GOSH provides over **60 different specialist and sub-specialist paediatric health services.** This was the widest range on any single site in the UK.

GOSH had **more than 60 YPF members,** who were involved in **89 activities.**

GOSH employed an average of **5,357 full time equivalent staff** in 2022/23.

GOSH had **50 YPAG members,** who gave feedback and had **input into 45 research projects.**

By the end of 2022/23 GOSH had **stopped purchasing Desflurane anaesthetic medical gas,** contributing to lower emissions.

2022 /23

GOSH had **2,217 participants** in **933 active research studies.**

The GOSH Learning Academy offered over **17,000 additional learning opportunities,** more than 10 times the target.

98% of inpatients and **95% of outpatients** would recommend GOSH.

Volunteers contributed **10,260 hours,** equating to approximately **£123,000 of donated time.**

GOSH had **44,994 inpatient and day cases.**

And **238,719 outpatient attendances.**

Great Ormond Street Hospital Culture and Values

The Trust has developed the Always Values with our staff, patients and families that characterise all that we do and our behaviours with our patients and families and each other.

Our Always Values are that we are:

Diversity & Inclusion

Here at GOSH, we believe that improving lives for our patients begins with improving how we learn, work and grow as colleagues. So, we're changing. We know that we need to develop a more inclusive culture where everyone feels seen and heard. By growing an ever more diverse workforce, we'll have a greater range of perspectives and knowledge in our GOSH community, meaning that we can provide the children and young people at our hospital with even better care. At GOSH we have opportunities for our staff to engage with colleagues through the following networks: REACH (Race, Ethnicity and Cultural Heritage) ENABLED (Enhancing Abilities & Leveraging Disabilities Network), PRIDE & Women's networks.

Job title	
Directorate	Research & Innovation
Band	Band 7
Supervised by	Interim Head of Governance and Clinical Trials
Type of contract	Permanent
Hours per week	37.5
Location	R&D Office, Based at UCL GOSH Institute of Child Health
Budgetary responsibility	None
Manages	2 x Clinical Trials Co-ordinators

Main purpose of the job

This post is based in the Joint Research and Development (R&D) Office of Great Ormond Street Hospital (GOSH) and the UCL Institute of Child Health (ICH), originally created in response to 'The Medicines for Human Use (Clinical Trial) Regulations 2004'. The successful applicant will ensure that GOSH/ICH is fully GCP compliant. The Clinical Trials Manager will work directly with the Head of Governance, Clinical Trials and Contracts, Clinical Investigators, Pharmacy, and research staff providing guidance and be the first point of contact for operational oversight, GCP and clinical trials related enquires while also providing management support for all Clinical Trials of Investigational Medicinal Products (CTIMPs).

Key working relationships

Internal:
Head of Governance, Clinical Trials and Contracts, R&D Clinical Trials Coordinator, GOSH R&D/CRF QA manager, Contracts Manager, Deputy Director of Research & Innovation, GOSH Pharmacy, Chief/Principal Investigators, Research Nurses, GOSH R&D Finance, Clinical Trial Co-ordinators in specific clinical and academic units, and Clinical Research Facility staff

External:
Medicines and Healthcare Products Regulatory Agency (MHRA), Research Ethics Committees, Health Research Authority (HRA), UCL/UCLH Gene Therapy Forum, external service providers and vendors for clinical trials and external sponsors.

Main duties and responsibilities:

To ensure that Trust is in compliance with the EU Clinical Trials Directive and UK legislation (Medicines for Human Use Regulations) implementing Good Clinical Practice for CTIMPs. These are listed below but not limited to below:

- To set up and maintain effective quality systems for clinical trials, ensuring GCP compliance when GOSH/ICH is the sponsor or host for non-commercial CTIMPs. This includes set up, initiation, monitoring, close down and archiving of CTIMPs sponsored by GOSH/ICH and for the management of overall conduct for these types of clinical trials.

- To write and review reports in accordance to local guidelines and regulatory requirements on the set up, initiation, monitoring and close-down of clinical trials, including planning and implementing corrective and preventive actions and to follow up until resolution.

- To write and review SOPs for the conduct of research and ensure that the research staff working on GOSH sponsored trials are trained on it.

- To support all staff involved in CTIMPs including Pharmacy, Clinical Research Facilitators/Coordinators, Finance, Investigators and provide their team with very good knowledge of GCP, Pharmacovigilance and regulatory advice.

- To deliver training, and mentoring to staff conducting CTIMPs on clinical trials regulations and GCP conduct within GOSH/ ICH departments including the Clinical Research Facility.

- To lead on pharmacovigilance activities for clinical trials which includes ensuring appropriate reporting of Adverse Events, Suspected Unexpected Serious Adverse Reactions, GCP and protocol breaches, deviations, violations and premature withdrawal of protocol to the MHRA and Ethics, and implementing corrective and preventive actions.

- To ensure annual safety update reports and GCP compliance reports are prepared and sent adhering to national guidelines and regulatory requirements and updating the knowledge of the current regulatory requirement of Pharmacovigilance to ensure that the Trust is compliant.

- To ensure the Trust has systems and processes in place to ensure that CTIMPs are conducted and data processed in accordance with ICH GCP and regulatory requirements.

- To lead and support in organising and delivering of the GOSH/ICH GCP course and participate in the teaching on the GCP course and other training run by Joint R&D Office in relation to clinical trials and processes.

- To represent the Trust in external and internal meetings and workshops related to clinical trials and attend the conferences, seminars and courses to keep up to date with knowledge of regulatory and ethical requirements of clinical trials.

- To fully line manage the Clinical Trial Coordinator.

Specific Tasks and Responsibilities:

Management

- To fully line manage and support the Clinical Trials Coordinator with responsibility for appraisals, professional development, attendance and performance management, recruitment, etc.

- To manage the portfolio and workload associated with the coordination of the portfolio of clinical trials sponsored by the GOSH and ICH.

- To prioritise and allocation of new and existing Trust and ICH sponsored clinical trials to the Clinical Trials Coordinator on an ongoing basis, including workload management.

- To develop and train staff to ensure that management level sponsor activities are covered, and a good trials review/support service is provided.

- To play an active part in the R&D team within GOSH/ICH by supporting and enforcing collaboration between the various team members.

- To participate in the R&D training programme, including Good Clinical Practice.

Clinical Trials set-up

- To support Chief Investigators with applications for new clinical trials; be the first point of contact, offer advice on regulatory and ethical requirements, and identify appropriate steps until resolution.

- To support the Chief and/or Principal Investigators in the preparation and development of documents required to be submitted to regulatory and ethical authorities and other relevant committees for approval of CTIMPs.

- To provide support in the production of annual safety and progress reports on trials as necessary under the direction of the Chief Investigator

- Assist with budget setting and costing of clinical trials ensuring that sufficient funds and staff are being considered and Clinical Research Facility costs included in budget preparation for grant applications

- Analyse and make definite judgments on particularly complex study designs to determine which applicable current legislation must be taken into consideration.

- To provide support in the finalising of all trial agreements required to be in place prior to trial commencement, for GOSH/ICH sponsored CTIMPS.

Clinical Trials Conduct and Management

To provide operational oversight and expert advice for all Trust sponsored CTIMPs and hosted CTIMPs with all aspects relating to:

- Project initiation
- Protocol design and review
- Ethics and regulatory review
- Pre-Trial and Site Initiation Visits
- Project oversight for duration of study
- Pharmacovigilance
- Maintenance of Sponsors' files including archiving
- Ensure that all aspects of GCP and regulatory requirements are complied with at all times through provision of relevant training at start-up and initiation meetings for their

designated clinical trials, including the preparation and submission of clinical trial protocol amendments and by implementation of suitable monitoring activities.

- To lead and implement with support from the Head of Governance, Clinical Trials and Contracts in the implementation of a trial risk assessment program based on risk management approach to sponsorship and monitoring.
- Complete and assess Risk Assessment forms for potential CTIMPS to establish whether trial can be sponsored by GOSH or UCL, ensuring appropriate liability provision by the sponsoring organisation
- To ensure the quality control and review of key study documents including protocols, participant information sheets and regulatory and ethics committee submissions.
- To provide advice on pharmacovigilance, indemnity, risk assessment, regulatory registration and compliance.
- To facilitate the tracking and management of serious adverse events.

Communication

- To attend the monthly R&I Risk Action Group Meeting and R&D operations meeting.
- To initiate studies with protocol training and safety reporting
- To ensure Investigators and staff are notified about SOPs, policies and guidelines relevant to their role and log their receipt and understanding and provide necessary training for implementation.
- To produce progress reports on trials as necessary and for internal reporting

Monitoring and Audit

- Take responsibility for trial monitoring and audit supporting the Clinical Trials Coordinator and Research Governance staff
- In the event of a statutory inspection (MHRA, FDA, external sponsor etc.) for GCP, contribute to and participate in the preparation for the inspection, including preparation of the dossier prior to inspection.
- To assist in the development and maintenance of an inspection plan, in order to ensure that the Trust remains in a state of readiness for statutory inspection.
- To prepare the documentation necessary for audits and inspections by the Regulatory Authority, the MHRA, making sure all the clinical trial files are up to date and ready for inspection, training of staff and Investigators, participating in the actual inspection and preparation of response to submit to MHRA on inspections findings including detailed corrective and preventive plan of action and implementation.

- To plan and conduct internal GCP audits as part of Quality Assurance of clinical trials processes including SOP implementation, approvals and data integrity checks.

- Quality control of data (Source Data Verification).

- To manage and update the quality systems for CTIMPs ensuring implementation of UK regulations and take overall responsibility for maintenance and implementation of Standard Operating Procedures (SOPs), policies, guidelines and forms including version control, quality control review, revisions and archiving.

Knowledge

- To keep abreast of new legislation and government requirements relating to the set-up and conduct of CTIMPS in order to carry out the role and ensure that risks to the Trust for conducting such trials is minimal and can be managed properly.

- To obtain and maintain a good understanding of the Research Governance Framework and the relevant systems and procedures for R&D approval at GOSH/ICH.

To attend national meetings related to non-commercial CTIMPS.

This job description is intended as an outline of the areas of activity and can be amended in the light of the changing needs of the service and will be reviewed as necessary in conjunction with the post-holder.

Other information

Great Ormond Street Hospital for Children NHS Foundation Trust is a dynamic organisation, therefore changes in the core duties and responsibilities of this role may be required from time to time. These guidelines do not constitute a term or condition of employment.

The GOSH Learning Academy (GLA)

Staff education and training influences every stage of the patient journey. Be it the communication skills of the medical secretary planning a patients' stay, the multi-professional team caring for them on the ward, the leadership skills of our corporate and operational teams, or the administrator planning their transport home – each member of staff needs the up-to-date knowledge, skills, and capabilities to provide our patients with exceptional care. We have a number of opportunities for staff available through the GOSH Learning Academy:

NHS
Great Ormond Street Hospital for Children
NHS Foundation Trust

PERSON SPECIFICATION

This table lists the essential and desirable requirements needed in order to perform the job effectively. Candidates will be shortlisted based on the extent to which they meet these requirements. Evidence for suitability in the role will be measured via a mixture of application form, testing and interview.

GOSH Culture and Values	Essential	Desirable	Assessment method
Our Always values • Always welcoming • Always helpful • Always expert • Always one team	E	D	I/A/T
1) Knowledge and Understanding of diverse backgrounds and perspectives. 2) Understanding of Diversity and Inclusion challenges in the workplace. 3) Demonstrable contribution to advancing Equality, Diversity and Inclusion in the Workplace	**E**		**I**
Academic/Professional qualification/Training			
Degree in a life Sciences discipline or postgraduate qualification in a life sciences discipline	**E**		
ICH-GCP certification	**E**		
Experience/Knowledge			
Experience of working in a clinical trial environment in either a pharmaceutical company, NHS Trust or a university.	**E**		
Either practical experience of monitoring clinical trial activity or practical experience of the research process or direct involvement in the management / administration of clinical trials	**E**		
Clinical trial management experience	**E**		
Excellent knowledge of ICH GCP, EU clinical trials legislation and UK clinical trial regulations	**E**		
Good understanding of the Department of Health's Research Governance Framework and the HRA Approval process	**E**		
Knowledge of clinical trials in all phases	**E**		
Excellent knowledge in the working of Clinical Trials of Investigational Products	**E**		
Experience of managing and implementing quality control and quality assurance systems	**E**		

Experience in hosting or participating in regulatory inspections (MHRA, FDA, etc.)	**E**		
Understanding of the NHS R&D structure and functions		**D**	
Skills/Abilities			
Ability to evaluate risks inherent in clinical trials and decide those which should be prioritised to ensure that risks are properly managed	**E**		
Excellent communication and good presentation skills	**E**		
Excellent report writing skills	**E**		
Ability to analyse and rationalise research information and ability to take decisions in complex situations	**E**		
Ability to coach and mentor senior academic staff including consultants	**E**		
Ability to prioritise workload and plan ahead	**E**		
Excellent planning, organisation and negotiation skills	**E**		
Ability to provide Pharmacovigilance, GCP advice to a high standard	**E**		
Ability to work accurately, with strong attention to detail	**E**		
Ability to work both autonomously and as part of a diverse team.	**E**		
Self-motivated, with ability to work on own initiative, making decisions where appropriate	**E**		
Flexible working approach and adaptable to change.	**E**		
Commitment to team-working	**E**		
Ability to acquire new knowledge and skills	**E**		
Meticulous attention to details	**E**		
Leadership qualities	**E**		
Experience of staff supervision or line management	**E**		
Ability to coordinate and oversee the working practices of junior team members	**E**		
Understanding of financial concepts and needs relating to research funding, particularly clinical trials		**D**	

Criteria Key: Essential: **E** Desirable: **D**
Review Method: Application form: **A** Interview: **I** Test: **T**